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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,859	10/01/2008	Herbert Moessler	2006_1221A	9760

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EXAMINER	
LIEB, JEANETTE	
ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
10/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/587,859	MOESSLER ET AL.	
	Examiner	Art Unit	
	JEANETTE LIEB	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-15* is/are pending in the application.

5a) Of the above claim(s) *1-8 and 10* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *9 and 11-15* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *NONE*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restrictions/Elections

Applicant's election of Group II, claims 9-15 in the reply filed on September 02, 2011 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Additionally, applicants elected "age associated memory impairment" pursuant to the election requirement for the method of treatment for claims 9-15. Claims 9-15 are pending. Claims 9 and 11-15 read on the elected species. Claim 10 is withdrawn as corresponding to a non-elected species, and Claims 1-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on November 01, 2011. An action on the merits follows.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter. Claim 10 is a "use of a compound," which is not a statutory class of inventions.

Claims 9, and 11-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 11-15 provide for the use of the composition described in claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless-
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 9, and 11-15 are rejected under USC § 102(b) as being anticipated by Herath (WO2002/46767 A2).

Hearath et. al teach peptide compositions and methods for treating Alzheimer's disease (See Abstract). This reference also teaches that Alzheimer's disease is an increasingly prevalent form of neurodegeneration that accounts for more than 50%-60% of the overall cases of dementia

among people over 65 years of age (age-associated memory impairment) and that the peptide compositions of the can be administered to a mammalian subject, preferably a human adult at least 35, at least 50, at least 60 at least 70 or at least 80 (p. 5, lines 16-22). This reference teaches that ADPI's can be useful in treating Alzheimer's disease, and that the APDI-3.1 has the sequence LAV**NMVPFPR** (p. 53, Table IV, Claim 7, SEQ ID NO: 393). Hearath et. al. teach that the compounds or "agents" of the invention can be used to reduce the severity of one or more of the symptoms of Alzheimer's and that a test compound can prove its ability to improve cognitive ability of a person having Alzheimer's (p. 182, lines 6-15). Further the reference teaches that administration may be an oral route, or by any mucocutaneous linings, and that it may be administered together with other biologically active agents (p. 183, lines 7-13). This reference further teaches that peptides may be embodies in excipients such as water, oils, such as vegetable, peanut, animal, mineral or sesame oil)p. 185, lines5-9). Additional excipients include starch, glucose, lactose, sucrose, gelatin, malt, rice, flour, chalk, silica gel, sodium stearate, talc, dried skim milk, among other suitable excipients (p. 185, lines 11-16).

This reference meets the limitations of claims 9 and 11-15 if the dietary supplement mixture contains SEQ ID NO: 1 NMVPFPR. The claims are drawn to treatment of "age-associated memory impairment" or dementia, and they are able to be in a composition with other biologically active agents or added to food excipients (see specification p. 25, dietary supplements definition). Further, the claims are drawn to a mixture comprising "at least one of two peptides" defined by SEQ ID NO 1: NMVPFPR ***or*** SEQ ID NO: 2 ASAFQGIGSTHWVYDGVGNS.

As to claims 11-15, age-related memory loss is caused by neurodegeneration associated with age, and by treating Alzheimer's, the dietary supplement mixture treats the dementia symptom of age related neurodegeneration and supports healthy mental function.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g.,

In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937,214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 9 and 11-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,148,192 B2. Although the conflicting claims are not identical; they are not patentably distinct from each other.

Claims 1-10 are drawn to a dietary supplement comprising at least one of the peptides consisting of NMVPFPR and ASAFQGIGSTHWVYDGVGNS (Claims 1-8), and a method of treating age-associated memory impairment and supporting healthy mental function in the aging process (Claims 9-10).

This meets the limitations of Claims 9, and 11-15 because the sequences are identical, and the dependent claims are drawn to the same dietary supplement for treatment of the same disease, age-associated memory impairment.

Thus, the claims are unpatentable over US patent No. '192.

5. Claims 9 and 11-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,151,088 B2. Although the conflicting claims are not identical; they are not patentably distinct from each other.

Claims 1-10 are drawn to a dietary supplement comprising at least one of the peptides consisting of NMVPFPR and ASAFQGIGSTHWVYDGVGNS (Claims 1-8), and a method of treating age-associated memory impairment and supporting healthy mental function in the aging process (Claims 9-10).

The difference between the US patent '192 and the instant claims is that the US patent '088 does not recite the peptide SEQ ID NO 1: NMVPFPR.

Hearath et. al teach peptide compositions and methods for treating Alzheimer's disease (See Abstract). This reference also teaches that Alzheimer's disease is an increasingly prevalent form of neurodegeneration that accounts for more than 50%-60% of the overall cases of dementia among people over 65 years of age (age-associated memory impairment) and that the peptide compositions of the can be administered to a mammalian subject, preferably a human adult at least 35, at least 50, at least 60 at least 70 or at least 80 (p. 5, lines 16-22). This reference teaches that ADPI's can be useful in treating Alzheimer's disease, and that the APDI-3.1 has the sequence LAV**NMVPFPR** (p. 53, Table IV, Claim 7, SEQ ID NO: 393). Hearath et. al. teach that the compounds or "agents" of the invention can be used to reduce the severity of one or more of the symptoms of Alzheimer's and that a test compound can prove its ability to improve cognitive ability of a person having Alzheimer's (p. 182, lines 6-15). Further the reference teaches that administration may be an oral route, or by any mucocutaneous linings, and that it may be administered together with other biologically active agents (p. 183, lines 7-13). This reference further teaches that peptides may be embodies in excipients such as water, oils, such as vegetable, peanut, animal, mineral or sesame oil) p. 185, lines5-9). Additional excipients include

starch, glucose, lactose, sucrose, gelatin, malt, rice, flour, chalk, silica gel, sodium stearate, talc, dried skim milk, among other suitable excipients (p. 185, lines 11-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the NMVPFPR sequence taught by Herath. to the composition comprising the peptide of claim 1 (SEQ ID NO:2). One would have been motivated to add the peptide of Herath to the Peptide of claim 1 because both are known in the art to treat age-associated memory impairment.

There is a reasonable expectation of success that SEQ ID NO 2: and the peptide NMVPFPR will treat age-related memory impairment as effectively together in a dietary supplement mixture as SEQ ID NO: 2 of US patent '088 would treat it alone.

Thus, the claims are rendered obvious over the claims of the US patents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEANETTE LIEB whose telephone number is (571)270-3490. The examiner can normally be reached on 8:30am -5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEANETTE LIEB/
Examiner, Art Unit 1654

/Anish Gupta/

Primary Examiner, Art Unit 1654